COMMISSIONER FOR PATENTS UNITED STATES PATENT AND TRADEMARK OFFICE

P.O. Box 1450 BOX 1450 ALEXANDRIA, VA 22313-1450

COPY MAIL

FISH & RICHARDSON PC P.O. BOX 1022 **MINNEAPOLIS MN 55440-1022** SEP 0 1 2009

OFFICE OF PETITIONS

In re Patent No. 7,166,283

Issued: January 23, 2007 Application No. 10/625,105

Filed: July 22, 2003 Dkt. No.: 14539-006002 : ON PETITIONS under

: 37 CFR 1.183 and ON REOUEST : FOR RECONSIDERATION OF

: PATENT TERM ADJUSTMENT

This is a decision on the 1) Petition under 37 C.F.R. 1.183, requesting that the Office suspend the rules and consider on the merits a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d) filed more than two months from the date the above-referenced patent issued; and on the 2) APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d), both filed on January 22, 2009.

The petition under 37 CFR 1.183 is **dismissed**.

The request for reconsideration of patent term adjustment under 37 CFR 1.705(d) is dismissed as untimely filed.

Any request for reconsideration, whether directed to the decision on petition under 37 CFR 1.183 or to the decision on application for patent term adjustment under 37 CFR 1.705(d), must be filed within two months of the mailing date of this decision. Extensions of time under 37 CFR 1.136 are not permitted. See § 1.181(f).

BACKGROUND

On January 23, 2007, the above-identified application matured into U.S. Patent No. 7,166,283 with a revised patent term adjustment of 419 days. No request for reconsideration of the patent term adjustment indicated in the patent was filed within two months of the date the patent issued. Patentee now petitions under 37 C.F.R. § 1.183 to (i) suspend or waive the requirement of 37 C.F.R. § 1.705(d) that a Request for Reconsideration of Patent Term Adjustment be filed within two months of the date the patent issued; and (ii) consider the enclosed DETERMINATION OF PATENT TERM ADJUSTMENT - POST GRANT. Patentee references the recent decision in Wyeth v. Dudas, No. 07-1492 (D.D.C. Sept. 30, 2008) as the basis for the petition.

ON PETITION UNDER 37 CFR 1.183 TO WAIVE THE TWO-MONTH REQUIREMENT OF 37 CFR 1.705(d) The above-referenced patent issued on January 23, 2007. A request for reconsideration of the patent term adjustment indicated in the patent was not filed until January 22, 2009. Petitioner requests that the Office suspend the rules and consider on the merits the Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d) even though it was untimely filed more than two months from the date the patent issued.

The relevant regulation, 37 CFR 1.705(d), provides that:

If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues. (emphasis added).

By the express provisions of 37 CFR 1.705(d), a request for reconsideration of patent term adjustment must be filed within two months of the date the patent issued. It is undisputed that no such request for reconsideration was filed by March 23, 2007, the date two months from the date this patent issued, January 23, 2007. Rather, on January 22, 2009, significantly after the issuance of a decision in <u>Wyeth v. Dudas</u> on September 30, 2008, petitioner filed the instant request for waiver of the two-month requirement.

37 CFR 1.183 provides that:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(f).

35 U.S.C. 154, which requires the Office to provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director, authorizes the Director to establish the procedures for requesting such reconsideration. Those procedures¹

¹ 35 U.S.C. § 154(b)(3) provides that the USPTO shall: (1) prescribe regulations establishing procedures for the application for and determination of patent term adjustments under 35 U.S.C. § 154(b); (2) make a determination of any patent term adjustment under 35 U.S.C. § 154(b) and transmit a notice of that determination with the notice of allowance under 35 U.S.C. § 151; and (3) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination. Pursuant to the mandate and authority in 35 U.S.C. § 154(b)(3), the USPTO promulgated 37 C.F.R. § 1.705, which provides that: (1) the notice of allowance will include notification of any patent term adjustment under 35 U.S.C.

include, pursuant to 37 CFR 1.705(d), setting a two-month period for filing a request for reconsideration of the revised patent term adjustment indicated in the patent.

Having considered petitioner's arguments, it is concluded that waiver of the two-month requirement is not warranted. The primary basis for requesting waiver set forth by petitioner is the recent decision in <u>Wyeth v. Dudas</u>, No. 07-1492 (D.D.C. Sept. 30, 2008). Specifically, petitioner argues the "court's holding that the Office's interpretation of the statute and regulations governing patent term adjustment is in error occurred more than two months after the present patent issued. As a result, petitioner could not have reasonably presented a request for reconsideration of the patent term adjustment within the time period specified under 37 C.F.R. § 1.705(d)."

Petitioner has not explained why it could not have filed a Request for Reconsideration of Patent Term Adjustment within two months of the date the above-referenced patent issued. Apparently, petitioner's argument is that the basis for the Request for Reconsideration of Patent Term Adjustment is the <u>Wyeth</u> decision, which was entered after the issuance of their patent.

The fact that any relief ultimately granted in <u>Wyeth</u> would benefit patentee had they timely filed a request for reconsideration does not make the situation extraordinary. <u>Wyeth</u> followed the procedure set forth in 37 CFR 1.705 for requesting reconsideration of the patent term adjustment determination. Then, pursuant to 35 U.S.C. 154(b)(4)(A), <u>Wyeth</u> timely filed a complaint in District Court seeking judicial review of the Office's decision. A Memorandum Opinion and Order, the <u>Wyeth</u> decision of September 30, 2008, directed to the parties involved was issued.

Petitioner chose not to challenge their revised patent term adjustment within the two-month period. Petitioner's argument that they could not have filed a Request for Reconsideration of Patent Term Adjustment within two months of the date the above-referenced patent issued because the basis for the Request for Reconsideration of Patent Term Adjustment is the Wyeth decision, which was occurred more than two months after the issuance of their patent, is not persuasive.

Petitioner could have filed a Request for Reconsideration of Patent Term Adjustment as Wyeth did. It is acknowledged that petitioner may have chosen not to file a request for reconsideration based on a conclusion that the Office's interpretation of 35 U.S.C. § 154(b)(2)(A) was correct. Nonetheless, the fact that the District Court has now issued an Opinion contrary to the Office's interpretation does not make the situation extraordinary. This is not unlike any other situation where a patentee (or applicant) challenges a final agency decision and the decision upon judicial

^{§ 154(}b)(37 C.F.R. § 1.705(a)); (2) any request for reconsideration of the patent term adjustment indicated in the notice of allowance (except as provided in 37 C.F.R. § 1.705(d)) must be by way of an application for patent term adjustment filed no later than the payment of the issue fee and accompanied by (inter alia) the fee set forth in 37 C.F.R. § 1.18(e)(37 C.F.R. § 1.705(b)); and (3) if the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued.

review could have had applicability to another patentee (or applicant) had they taken such action. In fact, many patentees may be in the same situation as petitioner with respect to the <u>Wyeth</u> decision. In addition, given that the law only allows 180 days for both the filing of a petition and for the Office's consideration of that petition, petitioner's unexplained delay in filing the petition weighs against them.

Petitioner simply fails to articulate how their failure to file a request for reconsideration of patent term adjustment within two months of the issue date of the patent was due to an extraordinary situation. Petitioner cannot rely on Wyeth's actions or the <u>Wyeth</u> decision to establish that their situation was extraordinary.

The contention that a decision is in error is a basis for a timely request for review of the decision but does not justify a delay in seeking review of such decision.

The Office provided notice that petitions under 37 CFR 1.182 and 1.183 or requests for certificate of corrections under 35 USC 354 and Sec. 1.323 or 35 U.S.C. 255 and Sec. 1.324 are not substitute *fora* to obtain reconsideration of a patent term adjustment determination indicated in a notice of allowance if applicant fails to submit a request for reconsideration within the time period specified in Sec. 1.705(b) or to obtain reconsideration of a patent term adjustment determination indicated in a patent if a patentee fails to submit a request for reconsideration within the time period specified in Sec. 1.705. See 69 Fed. Reg. 21704, 21707 (April, 22, 2004).

In view thereof, the petition under 37 CFR 1.183 for waiver of the two-month requirement of 37 CFR 1.705(d) is <u>dismissed</u>.

Accordingly, consideration now turns to the Request for Reconsideration of Patent Term Adjustment under 37 CFR 1.705(d).

ON REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)," filed January 22, 2009. Therein, patentee requests correction of the patent term adjustment (PTA) indicated in the patent to 604 days.

On January 23, 2007, the above-identified application matured into U.S. Patent No. 7,166,283 with a revised patent term adjustment of 419 days. The instant request for reconsideration was filed more than two months after the issuance of the patent, on January 22, 2009.

No error in the printing of the patent has been shown. The patent term adjustment indicated on the patent reflects the Office's determination of patent term adjustment shown in the PAIR system for this application. 37 CFR 1.705(d) provides the sole avenue before the Office for requesting reconsideration of the Office's determination of patent term adjustment indicated in

the patent. Moreover, § 1.705(d) states that "any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section." Since the request was not filed within two months of the issue date of the patent, the request is properly dismissed as untimely filed.

CONCLUSION

It is determined that waiver of the requirement pursuant to 37 CFR 1.183 is not warranted. Accordingly, the request for reconsideration of the patent term adjustment under 37 CFR 1.705(d) filed more than two months after the issue date of the patent is dismissed as untimely filed.

Receipt of the fees required for the petition under 37 CFR 1.183 and the application for patent term adjustment is acknowledged.

The correspondence address indicated on the petitions differs from that contained in the official record. If patentee desires to receive future correspondence concerning this patent at an address other than that contained in the official record, the appropriate request for change of correspondence address must be promptly submitted. The instant decision is being dually mailed as a courtesy. However, all future correspondence concerning this patent will be directed to the correspondence address contained in the record until appropriate instruction to the contrary is received.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.

Alesia M. Brown Petitions Attorney Office of Petitions

CC: JACK BRENNAN

Fish & Richardson P.C. Citigroup Center 52nd Floor 153 East 53rd Street

New York, New York 10022-4611